

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/445, 174 04/24/00 VAN OMMEN

G 294-78

<input type="checkbox"/>	EXAMINER
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HM12/1029

WTI DER. C	ART UNIT	PAPER NUMBER
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RONALD J BARON
HOFFMANN & BARON
6900 JERICHO TURNPIKE
SYOSSET NY 117911655
DATE MAILED:*20*

10/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.**Commissioner of Patents and Trademarks**

Office Action Summary

Application No. 09/445,174	Applicant(s) VAN OMMEN et al.
Examiner CB Wilder	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Oct 5, 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 15-55 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 15-55 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>19</u>	20) <input type="checkbox"/> Other: _____

Art Unit: 1655

FINAL ACTION

1. Applicant's amendment filed August 15, 2001 in Paper No.18 is acknowledged. Claims 1-14 have been canceled. Claims 15-55 have been added. Claims 15-55 are pending. Applicant's amendments and arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections. Any rejection not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The information disclosure statement filed October 15, 2001 in Paper No. 19 has been entered and considered.

Previous Rejections

4. The claim rejections under 35 U.S.C. 112 second paragraph are withdrawn in view of Applicant's cancellation of the claims. The claimed rejections under 35 U.S.C. 102(b) are withdrawn in view of Applicant's cancellation of the claims. The claimed rejection under 35 U.S.C. 102(e) are withdrawn in view of Applicant's amendment of the claims. The claim rejection under 35 U.S.C. 103(a) are withdrawn in view of Applicant's amendment of the claims.

Art Unit: 1655

New Ground(s) of Rejections

**THE NEW GROUND(S) OF REJECTION WERE NECESSITATED BY APPLICANT'S
AMENDMENT OF THE CLAIMS:**

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 15-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is drawn to a diagnostic test kit and a probe for use in the diagnostic for detecting the presence of or predisposition for breast cancer, wherein a means is provided for detecting a deletion of a stretch of nucleotides from a BRCA1 gene in a sample, wherein said deletion comprises at least a major part of any one or all of exons 13, 14, 15, and 16, or at least a major part of exon 22 wherein said probe comprises a nucleotide sequence which is a fusion of two ALU elements of the BRCA1 gene. The claimed invention is also drawn to a method of determining the presence in a sample of a nucleic acid derived from a BRCA1 gene having a deletion of a stretch of nucleotides, comprising contacting said sample with at least one probe which alone or together

Art Unit: 1655

with a second means for detecting said deletion of a stretch of nucleotides from a BRCA1 gene, distinguishes between BRCA1 gene having said deletion and BRCA1 genes not having said deletions, allowing hybridization between said probe and aid nucleic acids to form a hybridization product and identifying the hybridization product, wherein said deletions comprises at least a major part of any one or all of exons 13, 14, 15, and 16 or at least a major part of exon 22. The disclosure of "a deletion comprising at least a major part of any one or all of exons 14, 15 and 16" are not described or disclosed in the specification. The specification at page 7 discloses that "a good marker for predisposition for cancer is the deletion which comprises at least a major part of exons 13-16". The specification at the "Detailed Description of the Invention" at page 8 describes examples of two large genomic deletions of the BRCA1 gene at exon 13 and exon 22. The specification at page 10 and page 12 further describes experimental procedures for detection of the exon 13 deletion and the exon 22 deletion. Likewise, Figures 1 and 3 illustrates wherein a major part of or all of exons 13 and 22 are deleted in the BRCA1 gene. The disclosure further associates these deletions with hereditary types of cancer. The specification however fails to describe or disclose any deletions of exons 14, 15 and 16. There is no indication anywhere in the specification, including the figures, that a deletion of any part of or all of exons 14, 15 and 16 have been determined or detected. The example fails to provide any evidence of such mutations of exons 14, 15 and 16 existing. Merely stating that "a deletion comprising at least a major part of any one or all of exons 14, 15 and 16 is a good marker for detecting predisposition for breast cancer" is not sufficient evidence to meet the requirements of 112, first paragraph. As set forth by the Court in *Vas Caih Inc. V. Mahurkar*, 19 USPQ2d 1111,

Art Unit: 1605

the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing a deletion of a major part of or all of exons 14, 15, and 16 in the BRCA1 gene as claimed in claims 15-55 of the specification fails to show that Applicant was, in fact "possession of the claimed invention" at the time the application for patent was filed.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

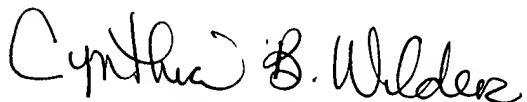
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The Examiner can normally be reached on Monday through Friday from 7:30 am to 5:30 pm.

Art Unit: 165

If attempts to reach the Examiner by telephone are unsuccessful, the Exr.'s supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.



Cynthia B. Wilder, Ph.D.

October 24, 2001



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600